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10/007,869	11/08/2001	Stewart Paton Granger	J6666(C)	6511

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/007,869	Applicant(s) GRANGER ET AL.	
	Examiner Shaojia A Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action (February 4, 2004) filed on March 25, 2004 is persuasive, since by an mere oversight, claims 2, 7, and 12 have not rejected in the last Office Action although these claims have been rejected in the First Office Action on the merits mailed April 9, 2003. Therefore, the finality of that action is withdrawn.

This Office Action is a response to Applicant's amendment and response filed on March 25, 2004 wherein claims 6-9 have been amended.

Currently, claims 1-18 are pending in this application.

Claims 1-18 are examined on the merits herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-7, 9-12, 14-15, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burger et al. (5,759,556, of record) and Granger et al. (5,716,627, of record) in view of Liu et al. (5,976,555, of record) and Surares et al. (5,941,116, of record).

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Burger et al. discloses a skin conditioning composition comprising a compound selected from retinol or retinyl ester in an amount from about 0.001% to about 10%, preferably in an amount from about 0.01% to about 0.5%, in combination with particular compounds such as instant retinoid booster: alpha lonones and Damascones (see particularly their structural formula at col.3-4 and col.2 line 41 to col.3 line 50, Example 6 at col.14) in an amount from about 0.0001% to about 50%; and a method of a skin condition selecting from the group consisting of dry skin, photodamaged skin, appearance of wrinkles, age spots and aged skin comprising applying topically to the skin the composition therein. See also abstract, col. 5 lines 23-28, and claims 1-4. Burger et al. also discloses the composition therein further comprising the instant emollients ranging from about 0.5-50% (see col.6 lines 23-56). Burger et al. further discloses that the skin care composition therein is stored in a suitable container to form a skin care product (see col.7 lines 20-42).

Granger et al. discloses skin conditioning compositions comprising a) retinol or retinyl ester in an amount from about 0.001% to about 10%, preferably in an amount from about 0.01% to about 1% (see particularly abstract, col.2 lines 31-40 and col.3 lines 34-39), b) an azole, most preferably climbazole (see particularly col.2 line 62, col.4 lines 19-27, col.12 Example 3 and col.14 Example 4) in an amount from about 0.001% to about 50%, preferably in an amount from about 0.001% to about 10%, and c) a fatty acid amide such as linoleoyl-DEA (also known as linoleamide DEA) in an amount from about 0.001% to about 50% (see particularly col.2 lines 36-38, col.12 Example 3 and col.14 Example 4), wherein at least two agents, an azole and the fatty acid amide,

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substantially improves the performance of retinol or a retinyl ester (see col.2 lines 47-50) and substantially increase the ability of either retinol or retinyl ester in skin benefit, resulting in a synergistic interaction between retinol or retinyl ester and fatty acid amides and azoles in treating skin conditions such as dry skin, photodamaged skin, appearance of wrinkles, age spots and aged skin (see col.2 lines 41-58); and a method of conditioning skin comprising applying topically to the skin the composition therein. See also claims 1-2 therein. Granger et al. further discloses that the skin care composition therein is stored in a suitable container to form a skin care product (see col.6 lines 24-25 and 33-35).

Burger et al. and Granger et al. do not expressly disclose the first compartment for storing retinol or retinyl ester kept out of contact with oxygen, and the second compartment for storing alpha lonone, and the first and second compartments being joined together; and avoiding chemical degradation of retinol or retinyl ester in the first composition that would be caused by contact with alpha lonone in the second composition. Granger et al. does not expressly disclose the employment of the particular fatty acid amide, Cocamide DEA, in the composition of prior art.

Liu et al. teaches that retinoids including of retinol, retinyl ester and retinal in skin care compositions are unstable, i.e., quickly losing their activity and either oxidize or isomerize to non-efficacious chemical forms. See col.2 lines 40-53. As a result, several stable compositions for skin care are supplied in two bottles or two portions (separating retinoids from other ingredients) and are mixed together just prior to use (see particularly col. 2 lines 54-61).

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Surares et al. discloses that the first and second compositions are stored in respective separate containers, being joined together (see abstract and Fig.1-2). One of separate compositions may comprise retinol, retinol esters, or retinoic acid (see col.3 Table I, col.4 lines 59-64, and col.8 Table III).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ two compartments for separately storing retinol or retinyl ester in a first composition and dimethyl imidazolidinone in the second composition, and also to keep retinol or retinyl ester out of contact with oxygen.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ two compartments for separately storing retinol or retinyl ester in a first composition and dimethyl imidazolidinone in the second composition, and also to keep retinol or retinyl ester out of contact with oxygen since retinoids including of retinol, retinyl ester and retinal in skin care compositions are known to be unstable because they quickly lose their activity by, for example, either being oxidized or isomerizing to non-efficacious chemical forms according to Liu et al. Moreover, several known stable compositions for skin care are known to be supplied in two bottles or two portions (separating retinoids from other ingredients) to keep retinoids from chemical reactions with other ingredients (the first and second compositions are known to be stored in respectively separate compartments or containers, being joined together) and are mixed together just prior to use and, based the teachings of Liu and Surares. Therefore, one of ordinary skill in the art would have found it obvious to employ two compartments for separately storing retinol or retinyl ester in a first composition and

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alpha Ionone in the second composition to keep retinol or retinyl ester from reacting with alpha Ionone in order to preserve the stability of retinol or retinyl ester in the compositions, and also to keep retinol or retinyl ester out of contact with oxygen to avoid being oxidized by oxygen in the air in the air or some other locations. Thus, the teachings of Liu and Surares et al. have clearly provided the motivation to employ the separate compartments herein.

Additionally, one having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular fatty acid amide, Cocamide DEA, in the skin compositions of Granger et al. since fatty acid amides are broadly known to be capable of substantially improving the performance of retinol or a retinyl ester in the skin care compositions and resulting in a synergistic interaction between retinol or retinyl ester and fatty acid amides and azoles in treating skin conditions such as dry skin, photodamaged skin, appearance of wrinkles, age spots and aged skin according to Granger et al. Cocamide DEA is a known and art-recognized fatty acid amide used in the skin composition, which is a coco fatty acid diethanolamide (having registry number 68603-42-9 of ACS, PTO-892). Thus, Cocamide DEA would have same or substantially similar usefulness or activity as linoleoyl-DEA (also known as linoleamide DEA) in skin care compositions, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g., Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214.

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Claims 3, 8, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burger et al. (5,759,556, of record) in view of Liu et al. (5,976,555, of record) and Surares et al. (5,941,116, of record) and Remington's Pharmaceutical Sciences (1990, of record).

The same disclosure of Burger et al. (5,759,556) has been discussed above (see *supra* at page 5 of the instant Office Action).

The same teachings of Liu et al. and Surares et al. have been discussed above (see *supra* at page 6 of the instant Office Action).

Above three cited references do not expressly disclose the first compartment made out of aluminum.

Remington's Pharmaceutical Sciences (1990) teaches that aluminum containers are widely used in pharmaceutical products for preserving the stability of many pharmaceuticals (see the bottom of the right column at page 1511 to the 1st paragraph of the left column at page 1512).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ an aluminum container as the first compartment for storing retinol or retinyl ester.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ an aluminum container as the first compartment for storing retinol or retinyl ester since Remington's Pharmaceutical Sciences (1990) teaches that aluminum containers are known to be widely used in pharmaceutical products for preserving the stability of many pharmaceuticals because one of ordinary

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skill in the art would clearly acknowledge that an aluminum container is stable, i.e., not reacting with many pharmaceuticals including retinol or retinyl ester in a normal storing condition and therefore is widely used as pharmaceutical containers (and/or food containers). Moreover, selecting a material for a container to store a pharmaceutical product from all known materials is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science and/or cosmetic science, involving merely routine skill in the art.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burger et al. (5,759,556, of record) in view of Granger et al. (5,716,627, of record) and Liu et al. (5,976,555, of record) and Surares et al. (5,941,116, of record).

The same disclosure of Burger et al. (5,759,556) has been discussed above (see supra at page 5 of the instant Office Action).

The same teachings of Liu et al. and Surares et al. have been discussed above (see supra at page 6 of the instant Office Action).

Burger et al. does not expressly disclose the employment of climbazole in the composition.

Granger et al. discloses skin conditioning compositions comprising a) retinol or retinyl ester in an amount from about 0.001% to about 10%, preferably in an amount from about 0.01% to about 1% (see particularly abstract, col.2 lines 31-40 and col.3 lines 34-39), b) an azole, most preferably climbazole (see particularly col.2 line 62, col.4 lines 19-27, col.12 Example 3 and col.14 Example 4) in an amount from about 0.001%

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to about 50%, preferably in an amount from about 0.001% to about 10%, and c) a fatty acid amide such as linoleoyl-DEA (also known as linoleamide DEA) in an amount from about 0.001% to about 50% (see particularly col.2 lines 36-38, col.12 Example 3 and col.14 Example 4); and a method of conditioning skin comprising applying topically to the skin the composition therein. See also claims 1-2 therein. Granger et al. also discloses that an azole such as climbazole, and a fatty acid such as linoleoyl-DEA substantially increase the ability of either retinol or retinyl ester in skin benefit, resulting in a synergistic interaction between retinol or retinyl ester and fatty acid amides and azoles in treating skin conditions such as dry skin, photodamaged skin, appearance of wrinkles, age spots and aged skin (see col.2 lines 41-58). Granger et al. further discloses that the skin care composition therein is stored in a suitable container to form a skin care product (see col.6 lines 24-25 and 33-35).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ climbazole in the second composition.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ climbazole in the second composition, since Granger et al. discloses that an azole such as climbazole, substantially increase the ability of either retinol or retinyl ester in skin benefit, resulting in a synergistic interaction between retinol or retinyl ester and fatty acid amides and azoles in treating skin conditions such as dry skin, photodamaged skin, appearance of wrinkles, age spots and aged skin.

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Applicant's remarks filed on filed March 23, 2004 with respect to the prior art rejections made under 35 U.S.C. 103(a) as being unpatentable over the cited prior art above have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for. These remarks are believed to be adequately addressed by the obvious rejection presented above.

Additionally, Applicant's testing data in the specification at pages 37-40 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art and but are not deemed persuasive. The results on the tests of the employment of the agents improving the performance of retinol or a retinyl ester and substantially increasing the ability of either retinol or retinyl ester in skin benefit, shown in Example 1 in the specification applied to a person have been taught and suggested by Burger et al. (5,759,556) and Granger et al. (5,716,627). Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). Therefore, the evidence presented in Examples herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

Moreover, the record contains no clear and convincing evidence of nonobviousness or unexpected results for the claimed product over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

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Note that arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a).

Therefore, said rejections are adhered to.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No.

5,759,556 (Burger et al.) in view of Liu et al. (5,976,555, of record) and Surares et al. (5,941,116, of record) and Remington's Pharmaceutical Sciences (1990, of record).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a skin conditioning composition comprising a compound selected from retinol or retinyl ester in an amount from about

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0.001% to about 10%, in combination with particular cyclic aliphatic unsaturated compound such as alpha lonone in an amount from about 0.001% to about 10%; and methods of conditioning skin comprising applying topically to the skin the composition therein.

The claims of the instant application is drawn to stable skin care products containing a first composition comprising about 0.001% to about 10% of a retinoid selected from the group consisting of retinyl esters, retinol, retinal and mixtures thereof; a second composition comprising about 0.0001% to about 50% of at least one retinoid booster selected from the group consisting of the particular retinoid boosters such as alpha lonone; a first compartment for storing the first composition; and a second compartment for storing the second composition; the first and second compartments being joined together, and methods of conditioning skin employing the compositions herein.

The patent does not expressly disclose the first compartment made of aluminum for storing retinol or retinyl ester kept out of contact with oxygen, and the second compartment for storing alpha lonone, and the first and second compartments being joined together; and avoiding chemical degradation of retinol or retinyl ester in the first composition that would be caused by contact with dimethyl imidazolidinone in the second composition.

The same teachings of Liu et al. and Surares et al. and Remington's Pharmaceutical Sciences (1990) have been discussed above (see supra at page 7 of the instant Office Action).

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One having ordinary skill in the art at the time the invention was made would have been motivated to employ two compartments for separately storing retinol or retinyl ester in a first composition and alpha Ionone in the second composition, and also to keep retinol or retinyl ester out of contact with oxygen since retinoids including of retinol, retinyl ester and retinal in skin care compositions are known to be unstable because they quickly lose their activity by either being oxidized or isomerizing to non-
efficacious chemical forms according to Liu et al. Moreover, several known stable compositions for skin care are supplied in two bottles or two portions (separating retinoids from other ingredients) and are mixed together just prior to use based the teachings of Liu and Surares. Therefore, one of ordinary skill in the art would have found it obvious to employ two compartments for separately storing retinol or retinyl ester in a first composition and alpha Ionone in the second composition to keep retinoids from reacting with dimethyl imidazolidinone in order preserve the stability of retinoid compositions, and also to keep retinol or retinyl ester out of contact with oxygen to avoid being oxidized by oxygen. Thus, the teachings of Liu and Surares et al. have clearly provided the motivation to employ the separate compartments herein.

Additionally, one having ordinary skill in the art would have found it obvious to employ an aluminum container as the first compartment for storing retinol or retinyl ester since Remington's Pharmaceutical Sciences (1990) teaches that aluminum containers are known to be widely used in pharmaceutical products for preserving the stability of many pharmaceuticals. Moreover, selecting a material for a container to store a pharmaceutical product from all known materials is considered well in the competence

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level of an ordinary skilled artisan in pharmaceutical science and/or cosmetic science, involving merely routine skill in the art.

Thus, the instant claims 1-18 are seen to be obvious over the claims 1-4 of U.S. Patent No. 5,759,556 in view of Liu et al. (5,976,555, of record) and Surares et al. (5,941,116, of record) and Remington's Pharmaceutical Sciences (1990, of record).

Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/008,067 in view of Liu et al. (5,976,555, of record) and Surares et al. (5,941,116, of record) and Remington's Pharmaceutical Sciences (1990, of record).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to a stable skin care composition containing a first composition comprising about 0.001% to about 10% of a retinoid; and about 0.0001% to about 50% of at least one retinoid booster; and a cosmetically acceptable vehicle, wherein the stable skin care composition is contained in a package so that the composition is out of contact with oxygen and the package made out of aluminum, and methods of conditioning skin employing the composition.

The claim of the instant application is drawn to stable skin care products containing a first composition comprising about 0.001% to about 10% of a retinoid selected from the group consisting of retinyl esters, retinol, retinal and mixtures thereof; a second composition comprising about 0.0001% to about 50% of at least one retinoid booster selected from the group consisting of the particular retinoid boosters herein; a

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first compartment for storing the first composition; and a second compartment for storing the second composition; the first and second compartments being joined together, and methods of conditioning skin employing the compositions herein. Thus, the instant compositions comprise about 0.001% to about 10% of a particular retinoid and about 0.0001% to about 50% of particular retinoid boosters herein.

The copending Application No. 10/00,067 does not expressly disclose the first compartment made of aluminum for storing retinol or retinyl ester, and the second compartment for storing at least one retinoid booster, and the first and second compartments being joined together; and avoiding chemical degradation of retinol or retinyl ester in the first composition that would be caused by contact with retinoid booster in the second composition.

As discussed in the above obviousness-type double-patenting rejection (see above for example at page 14-15 of the instant Office Action), as the same reason as above, the teachings of Liu and Surares et al. have clearly provided the motivation to employ the separate compartments herein.

Thus, the instant claims 1-18 are seen to be obvious over the claims 1-5 of copending Application No. 10/00,067 in view of Liu et al. (5,976,555, of record) and Surares et al. (5,941,116, of record).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's remarks regarding obviousness-type double patenting (see page 16 of Applicant's response) that "Nevertheless, in the interest of progressing the present

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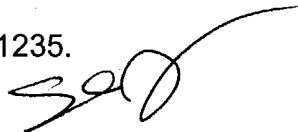
application to issue without delay, to the extent any double patenting rejections may remain, Applicants would be willing to supply a terminal disclaimer upon indication of allowability of the present claims.”, have been considered.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
April 27, 2004